EXHIBIT E

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE:
NEURONTIN MARKETING, SALES PRACTICES AND PRODUCTS LIABILITY LITIGATION) CA No. 04-10981-PBS
) Pages 107 - 360

DAUBERT HEARING - DAY TWO

BEFORE THE HONORABLE PATTI B. SARIS
UNITED STATES DISTRICT JUDGE
and
JUSTICE MARCY S. FRIEDMAN
NEW YORK SUPREME COURT

United States District Court
1 Courthouse Way, Courtroom 19
Boston, Massachusetts
June 20, 2008, 9:10 a.m.

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PROCEEDINGS

THE CLERK: In Re: Neurontin Marketing Sales Practices and Product Liability Litigation, Civil Action No. 04-10981, will now be heard before this Court.

MR. FINKELSTEIN: Your Honor, before we get started, two very fast issues. One, I'd like to hand up -- I've already provided it to Mr. Rouhandeh -- the declaration from Dr. Trimble related to simply the peer-review articles that he had referenced.

Secondly, we did offer an element where we think we can satisfy the time constraints we have. We agreed and suggested to defense counsel we limit 20 minutes to direct, 40 minutes to cross, and we could get everything in today, and we're open to doing that.

MR. ROUHANDEH: Your Honor, before that's handed up, the defendants believe it's entirely inappropriate for the witness to leave the stand, and then, before he gets on a flight to go back to London, signs a declaration to hand up to the Court when we don't have any opportunity to cross-examine him.

JUDGE SARIS: Overruled. If they're just the documents he referred to yesterday, I'm going to allow it.

MR. FINKELSTEIN: That's all it is.

JUDGE SARIS: It's very helpful. Let me just say this: We're having problems here. We both realized we read

something yesterday involving Dr. Taylor. And I read this single-spaced opaque report, and she got some really great little summary in an affidavit. So we're trying to figure out whether we're, A, getting the same documents, and, B, what we should be using to prepare for this hearing.

Did I get the affidavit? Does anyone know?

MS. McGRODER: Your Honor, Lori McGroder for the Pfizer defendants. The reason why you got affidavits in the New York court proceeding was because of the local rule about supporting our evidence with an evidentiary basis. So the experts provided affidavits setting forth what was in their reports. The substance is the same as in their actual reports which you received, your Honor.

JUDGE SARIS: But which is, like, ten times longer.

MS. McGRODER: Well, we'd be happy to give you the declarations also.

JUDGE SARIS: And the same comes up with Dr. Blume. It was 193 pages single-spaced. I didn't get through it, confession. I mean, you couldn't read it all, and it didn't really have a decent executive summary. So at some point, our time is a little limited here, and we're trying to move quickly to do catchup. So I don't know that I want 20 minutes. I don't know what she said. I mean, I didn't -- with some of them, you can read it through from beginning to end and just figure it out. I mean, if they're

(Discussion off the record.)
JUDGE SARIS: So do you have any idea what happened in 1999 that made that shoot up so dramatically off of a zero, almost of a zero base? Is that when it started getting marketed in a different way?
MR. BARNES: Let me direct some examination. I think I can teach you through this. Let me make a proffer. This is not even -- this is an incident. This is a percentage. It's not a proportion. What this represents is a percentage of this higher-level term as the percentage of the entire adverse event database. And so it's graphed over time, and it's based upon spontaneous adverse event reports, and it's used to generate to see if there is a signal, and there are lots of -- I want to talk about the method and its criticisms.
JUDGE SARIS: Yes, but I'm just asking. I mean, it's dramatic, actually. I just focused on it. Why does it suddenly shoot up for Neurontin? Do you know? I mean, if you don't know, you don't know. I'm not asking you. I'm just asking Dr. Blume. Do you know?
THE WITNESS: Oh, I'm sorry. I thought you were talking to him. Several things happened. There was new terminology put into the database, and also there was a publication.
JUDGE SARIS: A new terminology, all right, so they

were capturing more data?
THE WITNESS: Right, they were capturing more, and there was a publication regarding Neurontin-related intentional overdoses.
MR. BARNES: There was a Poison Center Control Report that at this time basically dumped in about 22 reports. It's a literature report, and it just came in at one time.
JUDGE SARIS: All right, okay, so that explains that, and then it sort of slowly creeps up and then jumps again. What happened there at around -- now that I'm seeing the dating that you used, in around March 31, 2002, maybe a little later, it jumps, starts going a steep incline again. Do you know why?
THE WITNESS: I'm turning to that section right now.
MR. BARNES: Your Honor, what statement are you concerned with?
JUDGE SARIS: You can see it right there. It looks like Mount Everest at the tail end there.
MR. BARNES: Right here?
JUDGE SARIS: Yes.
MR. BARNES: There's a dispute about publicity bias and when it was created. There was widespread advertising that began in 2003 and publicity.

JUDGE SARIS: So that's your view. Anyway, let me just say, Dr. Blume, I don't want to take his time. Do you have a ready explanation for that?
THE WITNESS: I'm looking to see it now, and I don't think the publicity was until the second half of 2003. I think those are the dates in which there was actually an impact of publicity. Just one second. I'm looking right now to see if I have specifically cited. . .
JUDGE SARIS: Anyway, if you see it later on, let us know. Maybe you can find it for redirect. I don't want to take his time to do it.
MR. BARNES: Thank you, your Honor. I've just offered another exhibit into evidence. I guess it's Defense Exhibit No. 3.
(Defendant Exhibit 3 received in evidence.)
MR. BARNES: Now, your Honors, I want to direct your attention to the first paragraph. This is an exchange of correspondence between Dr. Hauben of Pfizer and Dr. Brian Strom.
Q. I think we can agree, Dr. Blume, that Dr. Brian Strom is a recognized authority in pharmacovigilance in the United States, correct?
A. I do cite his book.
Q. So you would agree, and --
A. I don't know if he's ever been designated as an

authority in court, but I do cite his book.
Q. Okay. And in fact the plaintiffs at Page 35 of their briefing agree that Dr. Strom's textbook is authoritative. Let me show you what Dr. Strom says to Dr. Hauben about the use of proportional reporting ratios and measures of disproportionality such as the one that the Court was inquiring about. Here's what Dr. Strom says: "I strongly agree with Drs. Hauben and Dr. van Puijenbroek --"
JUDGE SARIS: Could you just fix that a little bit on the screen there.
MR. BARNES: Is that better?
JUDGE SARIS: And the "In reply" is --
MR. BARNES: It is a reply to Dr. Hauben, who's actually of Pfizer.
Q. And basically what Dr. Strom, an authority on pharmacovigilance who you cite says, "I strongly agree with Dr. Hauben and Dr. Puijenbroek that true signals should emerge from clinical judgment, and that statistical algorithms such as PRRs should be used as supplements to clinical and epidemiological judgment, not replacements. I also agree that the value of statistical algorithms, even in that role, remains unproven. Unfortunately, however, statistical algorithms are too often used alone, in publications and in the courtroom, as if they represent analyses useful for hypothesis testing, which is

inappropriate."
Do you agree with Dr. Strom, Dr. Blume?
A. Well, let me answer that step by step. I don't know to whom he's writing or the essence of this, but I will note that FDA in its Guidance instructs us to do PRRs -- just a second -- so we are instructed to do that. FDA says that you may examine PRRs for evidence of causation and in signal detection. And I agree that clinical and epidemiologic judgments would be wonderful to have, but in this case we can't have randomized clinical trials. And prior to the FDA's meta-analysis, I could find no epidemiology data associated -- found anywhere in your databases, so all we had were these type of data. But now we have the FDA epidemiologic review, and it confirms the PRR issues.
JUDGE SARIS: Well, do you agree that standing alone, these PRRs cannot establish general causation?
THE WITNESS: I agree that the PRRs are a tool in examining products across a series. That's the way I use them, or looking at differences within particular vulnerable subgroups.
JUDGE SARIS: Well, sure, but just as we just were doing going through that graph, it could be a difference in publicity, it could be a difference in reporting techniques.
THE WITNESS: Exactly, I agree.
JUDGE SARIS: I mean, the jumps look horrific when

you first look at them, but then there are explanations, right?
THE WITNESS: Right, I agree that they are a tool, but I would also agree that, your Honor, if you recall several years ago -- in fact they mentioned it -- the Bacol removal from the United States marketplace was predicated upon FDA's use of PRR ratios comparing Bacol and Lipitor. So that formed the basis of the product's removal.
JUDGE SARIS: It's a red flag.
THE WITNESS: It is a flag, yes, it's a flag.
JUDGE SARIS: And we all agree it's a useful red flag, but standing alone, you can't use it.
THE WITNESS: I would agree that we can't use it for statistical; but in a case such as when the end point is death and we can't have a randomized clinical trial, it's an end point that we have to look at.
JUDGE SARIS: Fair enough.
Q. Is it your testimony that -- what Judge Saris asked you was dead on. All these techniques do, if you accept them, is to say -- and there is some controversy as to whether or not they're even legitimate, as Dr. Strom points out -- you would agree that FDA does not believe and has never recommended in its Guidance document that these can be used as evidence of general causation?
A. Yes, I would agree with that, but I would also agree --

MR. FINKELSTEIN: Can she answer the question?
A. I mean, I would agree with that, but I would also point out in Dr. Strom's textbook, if you wanted to be complete, that Dr. Strom's textbook in fact is saying that even one -- he supports in his FDA chapter the use of such data and the use of post-marketing data when there's biologic plausibility to support causation. So he doesn't out of hand reject this. In fact he gives examples where post-marketing data, even limited post-marketing data, can be evidence of causation.
Q. Let's take it step by step. Dr. Strom is saying that the use of your technique for any purpose such as general causation is completely inappropriate. He even says it shouldn't even be used in a courtroom, correct? That's what he says?
A. You have read it correctly.
Q. Thank you.
A. I do not know the basis of this, but I know the extent of what he addresses in his book.
JUDGE SARIS: Now, who's this guy Strom again?
MR. BARNES: Dr. Strom is a --
JUDGE SARIS: You know, actually -- so who's Strom?
THE WITNESS: Dr. Strom is a well-recognized epidemiologist, and he publishes a textbook or a reference

book related to pharmacovigilance.
JUDGE SARIS: He's the guru in epidemiology?
THE WITNESS: He is, and what he does in his book is, he has FDA chapters, World Health Organization chapters, and he gets regulators as well as leaders in the field to talk on various topics. In the last two books, he has discussed the issue of causation, PRRs, dechallenge/rechallenge data. And I would submit that he finds great use for post-marketing data when we don't have anything else, especially when it's been confirmed by rechallenge data.
Q. Let me just finish one more question on this, just what Dr. Strom says. I want to finish reading what he says about your method, proportional reporting. Page 2, the same letter. This is Dr. Strom writing: "My central points remain. Case reports are primarily useful for hypothesis generation."
Now, Dr. Blume, that whole database that you were looking at was made up of MedWatch reports, which are essentially reports from doctors or patients about an experience with a drug, correct?
A. Well, they can be submitted by several people, but, yes.
Q. Yes, as an example. And here's what Dr. Strom says: "And I still concur with the observation of Hennessey that anecdotal case reports and disproportionality measures of